GEORGIA STATE BOARD OF PHARMACY
Board Meeting
Conference Call
Thursday, September 22, 2011
9:00 a.m.

Members Present:
Steve Wilson, President
Bill Prather, Vice President
Judy Gardner
Al McConnell
Tony Moye

Members Absent:
Pat McPherson
Ronnie Wallace, Consumer Member
Fred Barber

Staff Present:
Janet Wray, Board Attorney
Rick Allen, GDNA
Lisa Durden, Director
Eric Lacefield, Executive Director
Melanie Bradley, Board Support Specialist
Annie Ruth Parks, Licensing Analyst

Chairperson Steve Wilson established a quorum was present and called the meeting to order at 9:02 a.m.

Bill Prather made a motion, Judy Garland seconded, and the Board voted unanimously to enter into ***EXECUTIVE SESSION*** *in accordance with O.C.G.A. §§43-1-19(h) 2 and 43-1-2(k) to review applications, deliberate on disciplinary matters, and to receive information on investigative reports. Voting in favor of the motion were those present who included Board members Al McConnell, and Tony Moye.*

Executive Session

1. G.R.R. – Pharmacist. Board recommend to accept signed voluntary surrender.

At the conclusion of **EXECUTIVE SESSION**, Bill Prather made a motion to enter into **Open Session** to vote on the matters discussed in Executive Session and to conduct other Board business; Judy Gardner seconded the motion. Voting in favor of the motion were Tony Moye, and Al McConnell.

OPEN SESSION

Bill Prather made a motion to approve the recommendations made in Executive Session; Al McConnell seconded the motion. Voting in favor of the motion were Judy Gardner and Tony Moye.

Steve Wilson gave Executive Director, Eric Lacefield express permission to sign Board documents on his behalf.

Al McConnell made a motion to post the revision of **Rule 480-19**, and Bill Prather seconded the motion. The Board voted to post the revision of **Rule 480-19**.

*NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

Chapter 480-19 Exempt Schedule V Over-the-Counter (OTC) Controlled Substances, Amended.

480-19-.01 Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.
480-19-.02 Exempt Non-Pseudoephedrine Schedule V Controlled Substances.
480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine
480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine
480-19-.05 Exceptions to Exempt Schedule C-V Controlled Substance Drug Products Containing Pseudoephedrine Sales

480-19-.01 Excepted Sales of Non-Pseudoephedrine Schedule V Controlled Substances.
No person shall obtain or attempt to obtain, sell, dispense or otherwise dispose of any non-pseudoephedrine substance included in Schedule V of the Georgia Controlled Substances Act, except as herein provided, and as in compliance with all other applicable laws, rules and regulations~~; including Georgia Code Chapter 79A-8~~. All terms used in this section shall have the same meaning as in ~~Georgia Code Chapter 79A-8~~ O.C.G.A. T. 16, Ch. 14 and T. 26, Ch. 4, as amended.
(a) A physician or medical practitioner may dispense Schedule V substances for legitimate medical purposes in the normal course of his/her professional practice. ~~A physician or medical practitioner may administer Schedule V substances in their offices but cannot charge for the dispensed drug.~~
(b) A licensed pharmacist, or intern acting under the immediate and direct supervision of a licensed pharmacist, may sell, dispense or otherwise dispose of without prescription not more than 4 oz. or 32 dosage units of an exempted non-pseudoephedrine Schedule V controlled substance within any 48 hour period of time, but only:
1. After applying reasonable means or effort to determine that such is to be used for legitimate medical purpose**s**; and
2. After the purchaser has written his/her signature, date of birth, address, city, state and zip code upon a register which records and reflects the date of such transaction, the name, kind, quantity and intended use of such Schedule V substance sold, dispensed, or otherwise disposed of, and such records shall be maintained as required by Schedule V records.
(c) No person shall obtain or attempt to obtain, in any 48-hour period of time, more than 4 oz. or 32 dosage units of a Schedule V controlled substance.

Authority O.C.G.A. §§. 16-13-29.2, 26-4-27, 26-4-28.

480-19-.02 Exempt Non-Pseudoephedrine Schedule V Controlled Substances.
Before the sale of any non-pseudoephedrine Schedule V Controlled Substance without a prescription, a licensed pharmacist should first determine whether or not the product to be sold is packaged in a container with not more than 4 ounces or 32 dosage units of the drug, and whether the label provided by the product manufacturer contains a Federal Caution or Warning. If such Legend or Warning or Rx Only indication is present on the manufacturer's label, this product cannot be sold without a prescription.

Authority O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28.

480-19-.03 Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine

(a) No person shall obtain or attempt to obtain, sell, dispense or otherwise distribute any exempt Schedule V controlled substance drug product containing pseudoephedrine as listed under O.C.G.A. 16-13-29(5), except as herein provided, and as in compliance with all other applicable state or federal laws, rules and regulations. All terms used in this section shall have the same meaning as in O.C.G.A. T.16, Ch. 13 and T. 26, Ch. 4.

1) All exempt Schedule V controlled substance pseudoephedrine containing drug products must be stored in a pharmacy's prescription department.

2) All pharmacy personnel who engage in the sale or distribution of exempt Schedule V controlled substance containing drug products must complete the DEA's self-certification training as required by the Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C. 830.

(b) A registered pharmacist or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may sell, dispense or otherwise dispose of without prescription not more than 3.6 grams every 24 hours, or a maximum of 9 grams every 30 days, to each customer of a pseudoephedrine containing drug product, but only:

1) After applying reasonable means or effort to determine that such is to be used for legitimate medical purposes, following the proper record keeping procedures, and ensuring the required information has been properly recorded in a logbook which contains either a written or electronic list of sales.

2) For hand-written logbooks used to record patient information before the sale of an exempt Schedule V pseudoephedrine containing drug product can take place:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by writing in the logbook at a minimum the name of the pseudoephedrine containing drug product, strength, and quantity sold along with the name of the patient, their date of birth, address, zip code, data and time of sale; The pharmacy may require additional patient information for the logbook as long as the required information is obtained.

(B) The patient must sign the logbook to acknowledge the sale and receipt of the pseudoephedrine containing drug product.

(C) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy to, ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate identification

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must or may direct designated pharmacy personnel to verify that the date and time of the sale and other information that has been entered in the logbook is correct by use of the patient's photo identification, and initial the logbook verifying the information for the sale as being correct.

3) For electronic logbooks used to record patient information for the sale of an exempt Schedule V pseudoephedrine containing drug product:

(A) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist, must approve all such sales or transactions. Approval means verifying the patient's identification and ensuring the patient has a valid reason for obtaining the pseudoephedrine. After approval, the registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may direct designated pharmacy personnel, to complete any sales transactions to a patient by entering, at a minimum, the name of the pseudoephedrine containing drug product, strength, and quantity sold; the patient's name, date of birth, address, and zip code, or entering this information may be accomplished through a point of sales system and bar code reader. The pharmacy may require additional patient information for the logbook as long as the required information is obtained.

(B) The computer for the electronic logbook can automatically enter the date and time of the sale,

(C) The patient's signature on the logbook must be captured using an electronic signature system of a type similar to or one used for credit card purchases

(D) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist may personally, or may direct designated pharmacy personnel to, must ask the patient to produce a photo identification issued by a state or the federal government to use in verifying that the patient's name on the photo identification matches the name the patient wrote in the logbook; No exempt Schedule V pseudoephedrine containing drug product can be sold to a patient unless they present appropriate photo identification

(E) A registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist must, or may direct designated pharmacy personnel to, enter their name or pharmacist, pharmacy intern license number, or pharmacy personnel's identification in the logbook to indicate the information for the sale is correct.

(4) The quantities of different strength pseudoephedrine containing drug products that equals 3.6 grams is:

Tablets/capsules - Number of tablets/capsules that equal 3.6 grams

Ingredients	**Number of tablets = 3.6 grams**
30 mg Pseudoephedrine HCl	146 Tablets
60 mg Pseudoephedrine HCl	73 Tablets
120 mg Pseudoephedrine HCl	36 Tablets
30 mg Pseudoephedrine Sulfate	155 Tablets
60 mg Pseudoephedrine Sulfate	77 Tablets
120 mg Pseudoephedrine Sulfate	38 Tablets
240 mg Pseudoephedrine Sulfate	19 Tablets

Liquids -Number of milliliters that equal 3.6 grams

Ingredients	**Number of milliliters (ml) = 3.6 grams**
6.25 mg Ephedrine HCl/ 5 ml Liquid	3515 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	468 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	2929 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	1464 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	366 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	366 ml

(c) No registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist can knowingly sell more than 9 grams of pseudoephedrine to a patient in a 30 day period of time.

(1) The quantities of different strength pseudoephedrine containing drug products that equals 9 grams is:

Tablets/capsules - Number of tablets/capsules that equal 9 grams

Ingredients	**Number of tablets = 9 grams**
30 mg Pseudoephedrine HCl	366 Tablets
60 mg Pseudoephedrine HCl	183 Tablets

120 mg Pseudoephedrine HCl	91 Tablets
30 mg Pseudoephedrine Sulfate	389 Tablets
60 mg Pseudoephedrine Sulfate	194Tablets
120 mg Pseudoephedrine Sulfate	97 Tablets
240 mg Pseudoephedrine Sulfate	48 Tablets

Liquids -Number of milliliters in 9 grams

Ingredients	**Number of milliliters (ml) = 9 grams**
6.25 mg Ephedrine HCl / 5 ml Liquid	8788 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	1171 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	7323 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	3661 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	915 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	915 ml

(d) All logbooks must be retained for a minimum period of 2 years from the date of the last recorded sale.

(e) Logbooks must be kept in a secure location in the pharmacy and information contained in a logbook can be shared:

(A) To comply with state or federal laws and rules;

(B) For a product recall

(C) With local, state, and federal law enforcement officers, to allow logbook information to be inspected, copied.

(f) Nothing in this rule would prohibit pharmacies, or 3rd party information technology company acting on behalf of a pharmacy, to report or transmit sales data for exempt Schedule V controlled substance drug products containing pseudoephedrine to the state operated central registry, also known as the Georgia Methamphetamine Information System (GMIS). Without approval from GDNA, such data cannot be reported to any other central record keeping system. These sales may be reported to the registry either electronically, by means of transmitting a faxed copy of a handwritten logbook, or by sending copies of handwritten logbooks to the GDNA designated collection location for the registry via the U.S. mail or other similar means.

(g) Nothing in this rule requires a pharmacy to maintain a logbook that is separate and apart from the logbook required under the U.S. Combat Methamphetamine Epidemic Act of 2005, 21 U.S.C 830 and 844, other than drug products containing pseudoephedrine must be stored in the prescription department area of a pharmacy and the sales are made by a registered pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist.

Authority O.C.G.A. §§ 16-13-22, 16-13-29, 16-13-29.2,16-13-34, 26-4-27, 26-4-28.

480-19-.04 Record keeping for Over-the-counter (OTC) Sales of Exempt Schedule V Controlled Substance Drug Products containing Pseudoephedrine

(a) A record created this rule must be maintained in the pharmacy at which the transaction occurred, except that records may be kept either at a single, central location for the pharmacy or by a third party information technology company on behalf of the pharmacy only if the pharmacy has notified the GDNA of its intention to do so and received GDNA approval.

(1) Written notification must be submitted by registered or certified mail, return receipt requested, to the Director, Georgia Drugs and Narcotics Agency, 40 Pryor Street, SW, Suite 2000, Atlanta, Georgia 30303.

(2) This notification must include telephone and address contact information as well as a telephone number and email address for a point of contact person who is responsible for providing requested record for either the pharmacy's central record keeping location or any third party information technology company.

(3) The Director of the Georgia Drugs and Narcotics Agency shall issue written approval of any central record keeping location or third party information technology company prior to records being maintained in such a manner.

(b) The records required to be kept under this rule must be readily retrievable and available for inspection and copying by GDNA or other law enforcement officers as requested as provided for under the provisions of 21 U.S.C. 880, and the U.S. Combat Methamphetamine Epidemic Act of 2005.

(1) A record developed and maintained to comply with federal law may be used to meet the requirements of this rule if the record includes the information specified by this rule.

(2) Readily retrievable shall mean records must be produced by the pharmacy or the pharmacy's third party information technology company in less than 6 hours for all electronically maintained records or 24 hours for any handwritten records.

(c) If a pharmacy fails to produce records or produce records in the required time is considered a violation of O.C.G.A. Sections 16-13-37,16-13-39, and 16-13-42.

Authority O.C.G.A. §§. 16-13-22, 16-13-29, 16-13-29.2,16-13-34, 16-13-35, 26-4-27, 26-4-28, 26-4-60.

480-19-.05 Exceptions to Exempt Schedule V Controlled Substance Drug Products Containing Pseudoephedrine Sales.

(a) Any drug product containing pseudoephedrine which comes in a container packaged by the its manufacturer with and its label contains a Federal Caution or Rx Only indication, this product is not an exempt narcotic under this rule and cannot be sold as an Exempt OTC Schedule V drug product and can only be dispensed by a pharmacist, or pharmacy intern or pharmacy extern acting under the direct supervision of a registered pharmacist upon receipt of a prescription issued by a licensed practitioner.

(1) Such prescriptions should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

(b) Any licensed practitioner who is authorized to dispense drugs by O.C.G.A. 26-4-130 may dispense drug products containing pseudoephedrine in accordance to state laws and board of pharmacy rule 480-28.

(1) Such prescriptions dispensed according to board of pharmacy rule 480-28 should be filed and maintained in the manner set forth for Schedule III, IV or V controlled substance prescriptions.

Authority O.C.G.A. §§ 16-13-22, 16-13-34, 26-4-27, 26-4-28, 26-4-130

Bill Prather made a motion to post the following **Policy on Approval of Security Paper for Prescription Pads or Paper** as amended; Al McConnell seconded the motion, and the Board voted to post the following **Policy on Approval of Security Paper for Prescription Pads or Paper** as amended.

The Board voted unanimously to post the following **Policy on Approval of Security Paper for Prescription Pads or Paper** as amended:

All vendors, which produce security paper used in the printing or creation of pads of prescriptions to be used in this state, and which security paper contains all of the following criteria will be deemed to be an approved vendor by the Georgia State Board of Pharmacy:

(1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription form by the practitioner; and

(3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

By meeting all of the criteria identified above, a vendor may market and sell security paper for use in the production of prescriptions and prescription pads in this state provided the vendor notifies the Board in writing and provides the Board a copy of the product. If the Board determines that the paper submitted does not meet the requirements listed above, the Board will notify the vendor in writing. The Board will maintain a list of approved vendors.

All approved security paper shall have the Board's seal of approval affixed to the paper. The Board's seal of approval, as shown below, will be ½ inch in diameter, with the text in the seal being Georgia font, with the Rx within the circle being a size of 9 pt, with the text "GEORGIA STATE BOARD OF PHARMACY" within the circle capitalized with a size of 4 pt, and the text "SEAL OF APPROVAL" underneath the Rx with a size of 3 pt and capitalized.

The seal as shown below is the official seal:

All approved security paper used to print or create a prescription shall bear an identifying lot number, and each individual prescription shall be numbered sequentially beginning with the number one.

The security paper requirements shall not apply to:

(1) Prescriptions that are transmitted to the pharmacy by telephone, facsimile, or electronic means; or

(2) Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents of a nursing home, inpatients or residents of a mental health facility, or individuals incarcerated in a local, state, or federal correctional facility when the health care practitioner authorized to write prescriptions writes the order into the patient's medical or clinical record, the order is given directly to the pharmacy, and the patient never has the opportunity to handle the written order.

In the event a prescription pad or paper containing the Board seal, sequential numbering, and lot number is not available for the prescription and a medical health emergency exists, a prescription may be issued on paper meeting the requirements for approval for an amount of medication to cover not more than 30 days. The prescription must contain a statement that an emergency exists. All providers must have the board-approved security paper by December 31, 2011. This exception for emergencies only applies to prescriptions written before December 31, 2011.

The meeting adjourned at 10:05 a.m.

The next Pharmacy Board meeting will be Wednesday, October 12, 2011 at 10:00 a.m. at the Office of the Professional Licensing Boards, 237 Coliseum Drive, Macon, Georgia 31217.

_____ _____

Steve Wilson, President Date
The Georgia State Board of Pharmacy

_____ _____

Eric Lacefield, Executive Director Date
The Georgia State Board of Pharmacy